

March 26, 2007

Dr. Andrew C. von Eschenbach Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, Maryland 20857

RE: Control of Vibrio vulnificus in Gulf Coast Shellfish

Dear Dr. von Eschenbach:

The Center for Science in the Public Interest (CSPI) represents over 900,000 consumers in both the U.S. and Canada. The control of bacteria in the *Vibrio* family in Gulf Coast shellfish, especially oysters, is an important public health concern, but both the FDA and the Interstate Shellfish Sanitation Conference (ISSC) have failed to take action to protect consumers. We urge the FDA to immediately assert its authority over food-safety standards for molluscan shellfish by implementing mandatory post-harvest treatment that reduces the level of *Vibrio vulnificus* (Vv) levels to 3MPN/g or less.

FDA is currently doing nothing to address the life threatening risk posed by W in certain oysters. Instead, it is standing by while the ISSC implements the W Risk Management Plan for Oysters, adopted by ISSC in 2001. Under that plan, illnesses linked to Vv were to be reduced from the baseline rate of illness' by 40% for 2005 and 2006 (average) and 60% for 2007 and 2008 (average). The plan states that should the 60% rate of illness reduction goal not be achieved by 2008, one or more of the controls listed in the plan shall be implemented. The controls listed include post-harvest treatment to reduce W levels.

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<sup>&</sup>lt;sup>1</sup> Baseline rate of illness was calculated based on illnesses between the base years of 1995 to 1999.

The *Vv* Risk Management Plan is flawed and should be discontinued for the following reasons:

- California, one of four states originally included to measure the reductions in illnesses during the 2005-2008 time period, banned the sale of raw (untreated)
  Gulf Coast oysters in 2003 as too dangerous, and reduced their illness rate to zero.
  Thus the measurement of the plan rests on only three remaining states.
- 2. The *Vv* Risk Management Plan does not reflect national trends. In 2006, CSPI presented data at the International Association of Food Protection demonstrating the high level of variability between the data captured in the Risk Management Plan and national trends. For example, in the base years of 1995-1999, the percent of illnesses within the four target states averaged 68%, but in the years 2005-2006, they averaged 55%. Hence, illnesses and deaths are still occurring but more are happening outside the four target states than occurred during the baseline years.
- 3. Data from 2005 is inaccurate and cannot be included, since Hurricane Katrina wiped out the fall oyster harvest. At that time, it was estimated that it would take four to five years for the industry to reach its pre-Katrina harvesting levels.
- 4. Data from 2006 clearly document that the industry has not met the plan, even with the California ban and the reduced harvest. There were 31 illnesses and 14 deaths according to the latest available data in 2006, and this represents a reduction of only 28% of the goal, instead of 40%.

Given the clear public health problem documented by the CDC, CSPI strongly urges the FDA to take immediate risk management action to respond to the failure of ISSC to meet its target illness reduction rates. Waiting until the expiration of the risk management plan in 2008 is

unwarranted and presents a continuing danger to public health, since it is already clear that ISSC has fallen woefully short of its target reductions. FDA should immediately require controls to arrest the risk of *Vibrio* species in the food supply. Only by taking prompt action can the ISSC save many consumers from the devastating effects of Vv.

Sincerely,

Sarah Klein, J.D.

Food Safety Staff Attorney

cc:/ Ken Moore, Executive Director Interstate Shellfish Sanitation Conference

> Robert Brackett Food and Drug Administration

> Donald Kraemer Food and Drug Administration